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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,880	12/12/2003	John P. Fruehauf	02-1270-A	1031

7590 10/04/2005  
McDonnell Boehnen Hulbert & Berghoff  
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EXAMINER

YAO, LEI

ART UNIT PAPER NUMBER

1642

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/734,880

Applicant(s)

FRUEHAUF, JOHN P.

Examiner

Lei Yao, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12/12/03.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1 in part, 2, 13, 15, 17, 24-29, drawn to a method for identifying genes having an expression pattern in tumor cells that is **sensitive** to the chemotherapeutic agent, classified in class 435, subclass 4 and 7.23.
  - II. Claims 1 in part and 3, 13, 15, 17, 24-29, drawn to a method for identifying genes having an expression pattern in tumor cells that is **resistant** to the chemotherapeutic agent, classified in class 435, subclass 4 and 7.23.
  - III. Claims 4 and 11, drawn to a gene whose expression is increased in a cell **sensitive** to the chemotherapeutic agent, classified in class 536, subclass 23.1.
  - IV. Claims 5 and 12, drawn to drawn to a gene whose expression is increased in a cell **resistant** to the chemotherapeutic agent, classified in class 536, subclass 23.1.
  - V. Claims 6 -10, 14, 16, drawn to a method for identifying one or a plurality of genes having a different pattern of expression of a tumor cells comprising endothelial cell or stromal cells sensitive to a chemotherapeutic drug than the resistant to the chemotherapeutic drug, classified in class 435, subclass 4 and 6.
  - VI. Claims 18, drawn to a pattern of gene expression in a tumor cell **resistant** to chemotherapeutic drugs, taxanes, classified in class 435, subclass 4 and 6.
  - VII. Claim 19, drawn to a pattern of gene expression in tumor cell **sensitive** to a chemotherapeutic drugs taxanes, classified in class 435, subclass 4 and 6.
  - VIII. Claim 20 and 21, drawn to a method for identifying a tumor or cells comprising the tumor that are resistant to taxane, classified in class 435, subclass 4 and 6.
  - IX. Claim 22 and 23, drawn to a method for identifying a tumor or cells comprising the tumor that sensitive to taxane, classified in class 4, subclass 4 and 7.23.

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- X. Claims 30-39, drawn to a method for detecting and distinguishing a gene expression profile of living neoplastic cells resistant to a taxane cytotoxic, classified in class 435, subclass 4 and 6.

Inventions I, II, V, VIII-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods having different method steps and effects. Groups I and II are the method for identifying a gene expression in different population of cells, which are sensitive or resistant cells. Groups V and X are the methods of identifying and comparing a profile of gene expression in the sensitive to resistant neoplastic or other cell types which are involved in different method steps to separate the cells and identify different gene expression patterns. Group VIII and IX are the method of identifying tumor cells, which are sensitive or resistant to chemotherapeutic drugs. Each method has different method objective or different mode of operation. Search the method together would impose serious burden. The search required for one group is not required for the other Groups because each group requires a different non-patent literature search due to each group comprising different methods and steps, restriction for examination purposes as indicated is proper.

Inventions III and I, IV and II, VI and VIII, VII and IX are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the gene expression pattern in the cancer cells can be determined by a method having different method step as used in the groups I, II, VIII or IX or using different chemotherapeutic agent treating the tumor cells. Search the method of identifying the gene expression and expression pattern in the tumor cells are not coextensive which have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other Groups because each group requires

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a different non-patent literature search due to each group comprising different methods and steps, restriction for examination purposes as indicated is proper.

Furthermore, further **restriction** is required under 35 U.S.C. 121:

- A. If applicants elect group III, applicant must **elect one single gene** from the list in claim 4 or 11.
- B. If applicants elect group IV, applicant must **elect one single gene** from the list in claim 5 or 12.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to *different* products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of gene is a unique and separately patentable sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would constitute an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

**Applicant is advised that neither I – X nor A-B is species election requirements; rather, each is a restriction requirement.**

#### ***Election of Species***

This application contains claims directed to the following patentably distinct species of the claimed invention:

- A. propidium iodide, Annexin, fluorescent dye
- B. paclitaxol, taxol, or docetaxol
- C. EGFR or HER2.

In the event that applicant elects invention I, II, V, VIII, IX, or X, applicant is required under 35 U.S.C. 121 to elect a single disclosed species from A) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

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In the event that applicant elects invention I or II, applicant is required under 35 U.S.C. 121 to elect a single disclosed species from A) and C) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

In the event that applicant elects invention X, applicant is required under 35 U.S.C. 121 further to elect a single disclosed species from B) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitation of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. 821.04. Process claims that depend from or otherwise include all the limitation of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. thus, to be allowable, the rejoined claims must meet the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that process claims should be amended during prosecution either to maintain dependency on the product claims or otherwise include the limitation of the product claims. Failure to do so may result in a

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loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-4.30pm Monday to Friday.


Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.  
Examiner  
Art Unit 1642

LY

  
**JEFFREY SIEW**  
**SUPERVISORY PATENT EXAMINER**  
9/29/05